

REMARKS

The 35 USC 102b rejection

Claims 20-23, 25, 26-39 and 41-42 were rejected as being anticipated by York (US 5795594). Applicants traverse this rejection.

Current claim 20 claims a particulate coformulation of an active substance and an additive which is a solid dispersion of one in the other and that has a finite concentration gradient that increases radially outward from the core to the surface of the particles. York is directed to particles that are homogeneous mixtures of active and excipient. As exemplified in Examples 10 and 14, the matrices show a significant disturbance in salmeterol crystallinity (Fig. 32 and 33) compared to the pure salmeterol (Fig. 34). This is manifested by broadening of the spectral lines, indicating a significant degree of interaction between the drug and the polymer (a uniform dispersion), rather than a concentration gradient as required by claim 20 and its dependents. Since each element (in particular the concentration gradients) of claim 20 and accordingly each element of its dependents, claims 21, 22, 25, 26-39 and 41-42 are not described in York, the claims are believed to be novel over that reference.

The 35 USC 103 a rejection

Claims 20-39 and 41-42 were rejected as being obvious over York. Applicants traverse this rejection.

The current claims are directed to particles with a concentration gradient that increases radially outward. In this way a sensitive material would be protected from environmental influences and further, the particles could be successfully taste-masked. York makes no reference to either of these problems, or to any other kind of coating effect where one reagent is completely isolated from the external environment by an outer layer of another reagent. York is concerned with producing intimate mixtures (matrices) of actives and excipients. In view of York's process and emphasis on rapid and intimate mixing of the two components (see column 3 lines 40-44, column 5 lines 24-33, and the paragraph bridging column 10 and 11 and column 21 lines 16-18) the resultant particles would be homogeneous mixtures, not physically separated reagents or reagents having a concentration gradient. It would not have been obvious to produce particles using the process described in York. Accordingly, the rejection is believed to be inappropriate.

Conclusion

In view of the above, applicants respectfully request reconsideration and withdrawal of the 35 USC 102b and 103a rejections and allowance of the currently pending claims. The Examiner is invited to contact the undersigned attorney at the number below if it is believed that a telephonic interview would expedite prosecution of the present application.

Respectfully submitted,

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